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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,328	05/19/2005	Daniel Zimmerman	CS-118	3294

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EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,328	ZIMMERMAN ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/23/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I, peptide species SEQ ID Nos. 7, 9, and 18, treatment of infection by virus or phage, in the reply filed on 8/24/2007 is acknowledged. The traversal is on the ground(s) that PCT rule 13.2 applies only to election of groups, not election of species; that peptides SEQ 7, 9, and 18 are patentable over the Clayberger reference cited as defeating unity of invention; that SEQ 1-28 and the various treated conditions are not mutually exclusive; and that there is no serious burden involved in examination of all of the peptides and all of the diseases. This is not found persuasive because unity of invention determinations apply to species election as well as to groups of inventions, see for example Annex B of the Administrative Instructions Under the PCT, and MPEP 1850, particularly sections II and III involving Markush practice. In regard to the argument that the elected peptides are patentable over Clayberger, this does not change the conclusion that there is no special technical feature uniting the species recited in the main claim (claim 1), or uniting the methods in the two groups of claims. Mutual exclusivity is not required under unity of invention considerations. Please note, the common activity and significant structural element shared by SEQ ID NOs 7, 9, and 18 have been taken into consideration, which is why this examiner has permitted applicant to elect three species of peptide instead of the single species stated in the original restriction requirement. There is serious burden involved in examining all of the combinations of 28 peptides with 11 different kinds of disease conditions, as each requires different search; the prior art applicable to one

combination would not likely be applicable to another, and the various combinations are likely to raise different non-prior art issues under 35 U.S.C. U.S.C. 112, first paragraph.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-12, 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/24/2004.

Specification

The disclosure is objected to because of the following informalities: The specification contains numerous sequence recitations without the required accompanying SEQ ID designator. See for example pages 10 and 20-28. Also, the specification is incorrect in using SEQ ID NO:7 for the derG sequence presented on page 5, and in using nonspecific SEQ ID NOs 9 and 18 to refer to the specific sequences presented on pages 24 and 21. The confusion between specific sequence recitations and nonspecific SEQ IDs (with Xaa's) may extend beyond the sequences elected for examination.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection involves SEQ ID NO:7, 9, and 18. The specification states that SEQ ID NO:7 is the same as derG, with the sequence Asp Gly Gln Glu Glu Lys Ala Gly Val Val Ser Thr Gly Leu Ile. See page 5, paragraph 12. However, the Sequence Listing has a different structure for SEQ ID NO:7, (Asp or cyclohexylalanine or D- alanine) Gly Gln Glu Glu (Val or Leu or Ile or Gly or Ala) Ala Gly Val Val Ser Thr Gly Leu Ile. Note that the sequences are incompatible at residue 6. When the claims refer to "SEQ ID NO:7", it is not clear whether they refer to the derG sequence in the specification or to SEQ ID NO:7 in the Sequence Listing. Similarly, the specification refers to a specific sequence as SEQ ID NO 9 on page 24 and SEQ ID NO: 18 on page 21, but the Listing contains a broader general formula for SEQ ID NOs 9 and 18. Therefore the metes and bounds of the claimed subject matter are unclear. To reduce confusion in this Office action, the sequence found on specification page 5, paragraph 12, lines 3-4, will be called "derG", and the sequences found in the Listing will be called SEQ ID NO.___.

In addition, claim 17 is indefinite in reciting "compositions suitable for military applications." The specification provide provides no information as to what makes a composition suitable for military use. Therefore it is not clear what this claim is intended to cover or what it is meant to exclude.

Claims 13-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for use of derG or SEQ ID NO:7, 9, and 18 as an adjuvant and for a method of ameliorating zosteriform herpesvirus by administering derG before infection, does not reasonably provide enablement for the broadly claimed method for treating infections conditions. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claims are broadly drawn to a treatment method involving any of the peptides encompassed by SEQ ID NOs 7, 9, and 18. Applicant has shown that the mere change of Asn to Asp alters the biological activity of peptide G in an unpredictable manner. Therefore one skilled in the art would not believe without question that the amino acid alterations encompassed in SEQ ID NOS 7, 9, and 19 all have the same biological activity as peptide derG. The claims are also broadly drawn to a method for treating infectious conditions caused viruses or phages. This includes a vast number of disease conditions, differing widely in symptoms and etiology. The specification has one working example involving virus infection, showing that pretreatment of mice with derG reduces the extent of disease after herpesvirus infection. This provides little guidance for one skilled in the art seeking to treat an infected subject, since the example does not show whether the treatment method works after infection. Considering the broad scope of the claims, the limited guidance in the specification, the unpredictability of the art, and the limited scope of the working example, it is concluded that undue experimentation would be required to practice the full scope of the invention as claimed.

In addition, since phages infect prokaryotes (that lack immune systems), the specification completely fails to teach how to successfully treat an infectious condition caused by a phage.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman et al (Vaccine 19:4750-4759, issued 14 September 2001). Zimmerman teaches a fusion peptide where applicant's derG peptide is fused to an HIV peptide. The derG peptide acts as an adjuvant and immunomodulatory agent. This differs from the claimed invention in that Zimmerman does not actually treat an infectious condition. However, the reference explicitly suggests such a treatment method, see page 4757. Therefore the invention as a whole is prima facie obvious, absent unexpected results.

It is noted that applicants present an unexpected result for treating zosteriform herpes simplex virus infection in mice using the derG peptide. However, this unexpected result is not commensurate in scope with the claimed method.

Zimmerman et al WO 01/89286 is cited as of interest, in containing disclosure and suggestions similar to the Vaccine publication above, and additional suggestions regarding use of a derG conjugate or fusion peptide in a vaccine against herpes simplex virus, see e.g. page 4 and page 31.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 11/696124. Although the conflicting claims are not identical, they are

not patentably distinct from each other because the instant claims fully encompass the copending claims (note that SEQ ID NO:97 in the copending application is a species within the scope of SEQ ID NO:9 in this application).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 13-15 and 17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6572860 in view of Zimmerman et al WO 01/89286. US 6572860 claims a method of treating herpes simplex virus involving use of generic peptide, where peptide G (SEQ ID NO:5 in this application) is a species recited in the claims. See claim 6 and claim 3. This differs from the claims examined here, where derG and SEQ ID NOs 7, 9, and 18 involve modifications to the G peptide. However, WO 01/89286 teaches the improved response to the modified peptide derG. Therefore, use of the derG peptide in treatment of herpes simplex virus is an obvious modification of the patented method.

Claims 13-15 and 17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-9 of U.S. Patent No. 6951647. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims encompass the previously patented claims (note that the patent's SEQ ID NO:1 is the same as the current specification's derG).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mary E Mosher, Ph.D.
Primary Examiner
Art Unit 1648

9/19/07